

Notice of Allowability

Application No.

10/600,493

Examiner

Marc S. Zimmer

Applicant(s)

AUTRAN ET AL.

Art Unit

1712

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 06/20/03 and the interview conducted on June 24, 2004.
2. ☒ The allowed claim(s) is/are 1-20.
3. ☒ The drawings filed on 20 June 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

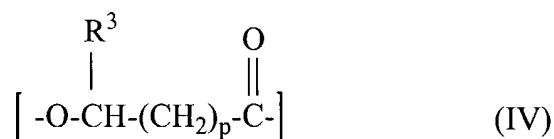
1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In claim 1, please remove the "R³" and "O" from the bottom of the first page of claim sheets and replace formula (IV) at the top of the second sheet with the following:



In the Specification, please replace Example 1 and all associated text with the following:

EXAMPLE 1

The present example demonstrates solution blended compositions and methods of the invention. The compositions comprise first and second PHA components. The first PHA component is a copolymer of 3-hydroxybutyrate (RRMU of formula (I) wherein R² is CH₃ and n=1) and about 6.1 mole percent 3-hydroxyhexanoate (RRMU of formula (II) wherein R² is C3), abbreviated as PHBHx copolymer. The second PHA component is isotactic polyhydroxybutyrate (i-PHB). Compositions 1A-1E are prepared as follows: (1A) solution-blending of the PHBHx copolymer and about 2.0 weight percent i-PHB in hot chloroform (50 °C), followed by solvent evaporation; (1B) solution-blending of the PHBHx copolymer and about 2.0 weight percent i-PHB in hot chloroform, followed by precipitation of the polymer out of the solution with chilled methanol; (1C) dry-blending of the PHBHx copolymer and about 2.0 weight percent i-PHB by mixing/grinding the powders in the presence of dry ice; (1D) masterbatch of solution-blended PHBHx copolymer containing about 15% weight percent i-PHB (prepared in hot chloroform),

which is then dry-blended with virgin PHBHx; and (1E) solution-blending of the PHBHx copolymer with 1 weight percent boron nitride, a conventional nucleating agent. For comparative purposes, a sample of the virgin PHBHx copolymer (composition 1F) is also prepared. Compositions 1A, 1B, 1C, and 1D are according to the invention while compositions 1E and 1F are for comparison purposes.

Using the Differential Scanning Calorimetry (DSC) technique described above to assess the rate of crystallization, the data set forth in Table I illustrate the rate of crystallization of compositions 1A-1F for a given optimal crystallization temperature (56.3°C), over a range of selected set temperatures prior to cooling. The half-time is the calorimetrically measured time it takes to reach about ½ full crystallinity, and the set temperature is the temperature at which the copolymer composition is equilibrated prior to being quenched to the crystallization temperature.

Table I: Crystallization half-time values for various PHA copolymer compositions

Set Temp. (°C)	130	140	150	160	170
Poly (3HB-co-3HX(6.1%)) + 2% i-PHB / via solution- blending + evaporation --- 1A	6	6	7	47	133
Poly (3HB-co-3HX(6.1%)) + 2% i-PHB / via solution- blending + precipitation --- 1B	7	8	8	69	171
Poly (3HB-co-3HX(6.1%)) + 2% i-PHB / via grinding + dry- blending --- 1C	18	31.5	71	120	129
Poly (3HB-co-3HX(6.1%)) + 2% i-PHB / sol. masterbatch + dry-blending --- 1D	19	32	69	138	196
Poly (3HB-co-3HX(6.1%)) + 1% boron nitride --- 1E	18	30	65	116	131

Neat Poly (3HB-co-3HX(6.1%))	--- 1F	24	36	84	168	220
------------------------------	--------	----	----	----	-----	-----

As evidenced by Table I, there is a rapid, consistent increase in $t_{1/2}$ in comparative compositions 1C-1F when the set temperature is raised from the original melting temperature of the PHBHx copolymer ($T_m \sim 127^\circ\text{C}$), even in the dry blended composition 1C and the conventionally nucleated composition 1E. On the other hand, compositions 1A and 1B exhibit very steadily low $t_{1/2}$ values up to greater than about 150°C , i.e. more than 20°C above the melting point of the original PHBHx copolymer. Hence, for these two systems, there is a processing temperature window of more than 20°C above the original melting temperature of the PHBHx copolymer (T_{m1}) where the half time for crystallization remains very low, i.e., below the measurable limit of the DSC method of ~ 5 sec. At higher melt temperatures and up to the original melting temperature of i-PHB (T_{m2}), compositions 1A and 1B containing solution-blended i-PHB continue to outperform the other blends, even though $t_{1/2}$ values are seen to progressively increase.

To further illustrate the solution-blended compositions of the invention and the dry-blended compositions, first scan heating isotherms for compositions 1A and 1C are recorded from 25 to 190°C , the results of which are set forth in Fig. 1. In the case of dry-blending, composition 1C, two well distinguished and separate melting endotherms are observed and are characteristic of the two separate components of the blends. On the other hand, in the case of solution-blending, composition 1A, a broadening of the PHBHx melting endotherm, combined with the appearance of intermediate melting species in the form of an expanded tail on the high-temperature side of the PHBHx, are observed and are indicative of structural changes in the blend. The temperature range defined by the high-temperature tail of the endotherm of composition 1A defines the preferred processing window over which the high nucleation benefit is observed.

Each of the claim amendments were needed to correct instances wherein the formula was spread over two pages. As for the amendment to the Specification, Example 1 originally had indicated that Example 1C, which refers to a system comprising PHBHx copolymer and i-PHB, was “prepared according to the method disclosed by Liggat in U.S. Patent # 5,693,389, using PHA copolymers of the present invention”. The Examiner raised concerns that this statement was an admission of prior art against claim 1 insofar as it seemed to suggest that Liggat disclosed the same combination of polymer materials as are claimed in claim 1 but possibly that they were blended under different conditions (see the final paragraph of Example 1). Because claim 1 does not recite any blending conditions, the Examiner explained that claim would be anticipated in view of Applicant’s apparent admission.

The Examiner also pointed out, on the other hand, that, in fact, Liggat does not appear to disclose the PHBHx copolymer or another polymer that would contain units (I) and also one of units (II) or (III) corresponding to the first polymer recited in claim 1. That is, Applicant’s admission of prior art against claim 1 was seemingly erroneous. Upon reviewing the text of Example 1, Applicant concurred saying that that only 1E and 1F were being offered for comparative purposes whereas Examples 1C and 1D were supposed to be exemplify the instant invention. The Examiner requested that Applicant make the appropriate changes in wording to reflect this position. The amendment above is intended to address the inadvertent suggestion that *Liggat* would anticipate claim 1 (and possibly numerous others).

Art Unit: 1712

Liggat does mirror the instant invention in virtually every respect including Applicant's impetus for mixing two polyesters having disparate melting points- the second serves as a nucleating agent to promote faster crystallization of the first- but, again, the lower melting polymer disclosed by the reference does not adhere to the structural limitations set forth for the lower melting polymer in the claim. The Examiner could not ascertain what would motivate one of ordinary skill to replace the lower melting polymer with one satisfying Applicant's requirements.

Figuly, U.S. Patent Application Publication No. 3003/0181555 teaches *precisely the same* polymer mixture and purports to *solve the same problem* that is addressed by Applicant's invention. See claims 1-5. However, the effective filing date for this invention does not antedate that of the instant invention.

The aforementioned patent documents represent, in the Examiner's view, the most closely related teachings known. Because they fail to even render obvious the claimed invention, or are invalid as prior art, claims 1-20 are deemed allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance." Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc S. Zimmer whose telephone number is 571-272-1096. The examiner can normally be reached on Monday-Friday 8:00-4:30.

Art Unit: 1712

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

June 25, 2004



MARGARET G. MOORE
PRIMARY PATENT EXAMINER
ART UNIT 1712